PCT/JP2003/003307

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference GP03-1001PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/JP2003/003307	International filing date (*day/month/year*) 19 March 2003 (19.03.2003)	Priority date (*day/month/year*) 29 March 2002 (29.03.2002)
International Patent Classification (IPC) or national classification and IPC C12N 15/09, C12Q 1/68, G01N 33/53, 33/566		
Applicant SYSMEX CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23 October 2003 (23.10.2003)	13 February 2004 (13.02.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP2003/003307

I. Basis of the report

1. With regard to the **elements** of the international application:*

☒ the international application as originally filed

☐ the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the claims:

pages _____, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the drawings:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____, which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/JP03/03307

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2, 3, 5-8, 11-13	YES
	Claims	1, 4, 9, 10	NO
Inventive step (IS)	Claims		YES
	Claims	1-13	NO
Industrial applicability (IA)	Claims	1-13	YES
	Claims		NO

2. Citations and explanations

Document 1: WO, 00-42220, A (The Regents of the University of California), 20 July, 2000 (20.07.00)
Document 2: Rapid Mutation Detection by the Transgenomic Wave Analyser DHPLC Identifies MYOC Mutations in Patients with Ocular Hypertension and/or Open Angle Glaucoma, (C. J. Cobb, et al.), Br. J. Ophthalmol., February 2002, Vol. 86 (2), pages 191-195
Document 3: Analysis of Myocilin Gene Mutations in Japanese Patients with Normal Tension Glaucoma and Primary Open-angle Glaucome, (F. Mabuchi et al.), Clin. Genet., April 2001, Vol. 59 (4), pages 263-268
Document 4: Novel Mutations in the Myocilin Gene in Japanese Glaucoma Patients, (R. Kubota et al.), Hum. Mutat., September 2000, Vol. 16 (3), page 270
Document 5: Age-dependent Prevalence of Mutations at the GLC1A Locus in Primary Open-angle Glaucoma, (S. [illegible] et al.), Am. J. Ophthalmol., August 2000, Vol. 130 (2), pages 165-177
Document 6: [illegible]s of Myocilin Mutations in 1703 Glaucoma Patients from Five Different Populations, (J. [illegible]m. Mol. Genet., May 1999, Vol. 8 (5), pages 899-905
Document 7: [illegible]268STOP Myocilin Mutation in Families with Late-onset Primary Open-angle Glaucoma, (R. R. Allingham, et al.), Invest Ophthalmol. Vis. Sci., November 1998, Vol. 39 (12), pages 2288-2295
Document 8: GLC1A Mutations Point to Regions of Potential Functional Importance on the TIGR/MYOC Protein, (F. W. Rozsa, et al.), Mol. Vis., 6 October 1998 (06.10.98), Vol. 4, page 20

(1) The subject matters of claims 1, 4, 9 and 10 do not appear to be novel or to involve an inventive step in view of document 1 cited in the ISR.

Document 1 discloses that base mutations at two or more points in the domain upstream of the sequence to code for TIGR protein, which is a glaucoma-associated-gene, are detected to predict the future onset of glaucoma.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of : V

(2) The subject matters of claims 2, 3, 5-8 and 11-13 do not appear to involve an inventive step in view of documents 1-8 cited in the ISR.

Document 1 discloses that base mutations at two or more points in the domain upstream of the sequence to code for TIGR protein, which is a glaucoma-associated-gene, are detected to predict the future onset of glaucoma. In addition, documents 2-8 disclose that, in the myocilin gene, which is a glaucoma-associated-gene, a variety of mutations related to the onset of glaucoma have been found.

A person skilled in the art could have conceived of analyzing the mutations of the myocilin gene disclosed in cited documents 2-8 by means of a technique similar to that disclosed in cited document 1 in order to predict the onset of glaucoma. A person skilled in the art could have conceived of detecting other mutations of myocylin genes from glaucoma patients and of using them for such prediction by means of a technique similar to those disclosed in cited documents 2-8, in view of cited documents 1-8.